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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,230	01/27/2004	Jean-Yves Guy Christophe Blay	SF06000US01	2928
24265	7590	08/11/2006	EXAMINER	
SCHERING-PLOUGH CORPORATION PATENT DEPARTMENT (K-6-1, 1990) 2000 GALLOPING HILL ROAD KENILWORTH, NJ 07033-0530			CANELLA, KAREN A	
			ART UNIT	PAPER NUMBER
			1643	

DATE MAILED: 08/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/766,230

Applicant(s)

BLAY ET AL.

Examiner

Karen A. Canella

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 1-8, 11, 12 is/are rejected.
- 7) ☐ Claim(s) 9 and 10 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claims 1-12 are pending and examined on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4 are rejected under 35 U.S.C. 102(e) as being anticipated by Mellor et al (WO 03/087347).

Claim 1 is drawn to a method for making a prognosis of disease course in a human patient having cancer comprising detecting infiltration of a tumor by plasmacytoid dendritic cells (pDC) wherein infiltration by plasmacytoid dendritic cells is prognostic of the aggressiveness and mortality of the cancer. Claim 2 embodies the method of claim 1, wherein said detecting comprises the steps of (a) obtaining a sample of a tumor from the human cancer patient; and (b) detecting infiltration of the tumor sample by plasmacytoid dendritic cells (pDC). Claim 3 embodies the method of claim 2, wherein said detecting comprises testing for specific pDC markers. Claim 4 embodies the method of claim 3, wherein said specific pDC markers are selected from the group consisting of CD123 and BDCA2.

Mellor et al discloses a method for assessing the relative risk of tumor progression in a subject, said method comprising the detection of CD123 (claims 107-109). It is noted that the detection of the CD123 marker fulfills the specific embodiment of detection of infiltration of the plasmacytoid dendritic cells by an indirect means

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 7, 8, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lissoni et al (Journal of Biological Regulators and Homeostatic Agents, 1999, Vol. 12, pages 213-219).

Claim 7 embodies the method of claim 1, wherein said detecting of infiltration of a tumor by plasmacytoid dendritic cells (pDC) comprises testing for specific pDC markers in the circulating blood. Claim 8 embodies the method of claim 7, wherein the specific pDC markers are selected from the group consisting of CD123 and BDCA2.

Claim 11 embodies the method of claim 1, wherein the cancer is primary breast cancer. Claim 12 embodies the method of claim 11 wherein the cancer is primary invasive, non-metastatic breast cancer.

Lissoni et al disclose a method for making a prognosis of a disease state comprising the detection of dendritic cells in the blood by means of detecting the CD123 antigen (abstract, last sentence, and page 218, first column, lines 4-16). Lissoni et al disclose that metastatic patients had an abnormally low percentage of CD123 cells (page 218, first column, lines 1-3 under the

heading of "Results"). Lissoni et al include breast cancer patents in the result (page 214, Table 1) which fulfills the specific embodiments of claim 11 and 12.

Claims 1-3, 5, 6, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mushinski et al (WO 03/033667).

Claim 5 embodies the method of claim 2, wherein said detecting comprises testing for secondary pDC markers. Claim 6 embodies the method of claim 5, wherein said secondary pDC markers are selected from the group consisting of type 1 IFN and MXA.

Mushinski et al teach method of assessing the metastatic potential of a cancer by obtaining a sample of the cancer, determining the level of Mx, in the sample, and assessing the metastatic potential of the cancer by comparing the level of Mx with a control (page 3, lines 3-6 and claim 3). Mushinski et al teach that Mx includes MxA (page 6, last line). Mushinski et al teach that cancer cells expressing MxA have a reduced metastatic potential as compared to cancer cells that do not express MxA (page 34, paragraph 0092). Mushinski et al teach that the method can be used to determine breast cancer progression (page 6, lines 4-5).

It would have been prima facie obvious at the time that the claimed invention was made to make a prognosis of a disease course, wherein said disease was cancer or specifically breast cancer by determining the metastatic potential of said cells by assaying for MxA. One of skill in the art would have been motivated to do so by the teachings of Mushinski et al regarding the relationship between the expression of MxA and metastatic potential in cancer cells. One of skill in the art would understand that a patient harboring cells with increased metastatic potential has a poor prognosis relating to disease progression.

Claims 9 and 10 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Art Unit: 1643


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Karen A. Canella, Ph.D.

8/6/2006


KARENA CANELLA PH.D
PRIMARY EXAMINER